Legal Distinctions between Clinical Research and Clinical Investigation:

Lessons from a Professional Misconduct Trial

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Abstract

A senior Fellow of the Royal College of Physicians, London was accused of professional misconduct and ordered to be erased from the U.K. medical register following a fitness to practice trial by the General Medical Council (GMC). He was charged with performing clinical research without ethical approval. The Defendant claimed his actions were based on clinical need to investigate his patients' atypical symptoms and signs. Flaws are described in the trial that favoured the GMC to win the case after five years of trial. These included lack of impartiality, bias against the Defendant's Expert Witness, restricted access to evidence and unwarranted time delays. At Appeal before the High Courts in London the charges and sanctions by the GMC were quashed within four days of public hearings. The difficulty of defining clinical research as distinct from clinical investigation of patients is discussed with reference to the GMC trial and subsequent ruling by the High Courts.

Keywords

Law; General Medical Council U.K.; Ethics of Clinical Research; Clinical Investigation

Introduction

The General Medical Council (GMC) is a statutory body answering to the Parliament of the United Kingdom whose remit is to investigate the misconduct of doctors and to ensure good medical practice (www.gmc-uk.org). Part of their work involves publishing rules doctors must follow under threat of being expelled from the medical profession so losing their vocational means of livelihood. The following is a case-study where an initial verdict of professional misconduct involving clinical research without ethical approval was brought against a distinguished Australian paediatrician, Professor Walker-Smith M.D., F.R.C.P lasting 5 years of trial. It shows how a powerful organisation such as the GMC can contravene the basic rules of a fair and just trial in order to win their case; and even when the charges and sanctions are quashed by the High Court of Appeals they do not acknowledge misapplications of their trial procedures.

General Medical Council v Walker-Smith (2004-2010).

The charge of serious professional misconduct brought by the General Medical Council against Professor Walker-Smith was that he authorised standard medical procedures considered by them to be research not in the clinical interests of twelve of his young patients and having no approval by an ethical committee (Walker-Smith SPM.pdf 32595970 pdf). Professor Walker-Smith directed an academic tertiary referral unit for bowel disorders in children and patients were referred to him by other doctors for further investigations and management, which for various reasons were best carried out in specialist centres. The children under study were suffering from an atypical combination of bowel problems and autistic-like disorders; and as physician in charge of the cases with these symptoms and signs, he considered that colonoscopies were indicated to determine whether the children had bowel inflammation and neurological tests including a lumbar puncture to exclude brain mitochondrial enzyme defects.

The GMC rule appears to be that procedures ordered by doctors to establish diagnoses are in the best clinical interests of patients and do not need ethical approval; whereas procedures aimed at investigating the cause(s) of disease, as is the case here, are not in the best interests of the patients unless authorized by an ethical committee. If such rules were strictly

enforced progress in medical care and knowledge would steeply decline. Investigating the determinants of a patient's disease can be a more important activity than treating known disease because the results if successful may apply therapeutically to this particular patient as well as to other groups of children suffering from unusual types of bowel or brain disorders.

As for many problems in clinical medicine there are fine dividing lines to be drawn between clinical care, investigation into the cause of disease, and research procedures that require ethical approval. The latter most clearly include the use of novel technology or the use of new therapeutic agents that are unrelated to any condition that the patient might have, which was never the case here.

Flaws in the Fitness to Practice Trial by the GMC.

Competence and Independence of the Judges.

The professional panellists selected as Judges by the GMC appeared to have very little knowledge or expertise in the problems under review. The field of paediatric gastroenterology is highly specialised and it is difficult to see how a Consultant Adult Psychiatrist, a retired Geriatrician and a Family Practitioner (the chairman) could have had much first-hand clinical experience into the pitfalls of such a practice or ever have been faced with the elucidation of the complex aetiology of these conditions. The other two members of the panel (a Local Authority Chief Executive and an Independent Mediator) would be heavily dependent on the medical members for knowledge and opinions that distinguish medical investigation from medical research, which forms the basis of this trial. For the Defendant to need to explain the meaning of elementary terms in common gastrointestinal usage such as 'lamina propria' or 'intestinal crypt' to the panel as observed by author DJG at a public hearing suggests there is a serious imbalance of knowledge between the Defendant and the panel of Judges. The panel members also appeared to be unaware of current practice in the use of colonoscopy. An enquiry into colonoscopy practice at the Defendant's hospital where author JAD was an outside independent chairman confirmed that Walker-Smith's department practised well within the range of variation in UK centres of Paediatric Gastroenterology.

The panel as a whole should be seen to be impartial, authoritative, independent and in a position to pass an appropriate sentence (acquittal, reprimand, suspension or erasure). However the panel of Judges was selected by, working for, and paid by the GMC. The GMC is now assuming the roles of both prosecutor and judge, by bringing the charges of professional misconduct and seeking erasure of the Professor by their appointed panel, which appears not to be an impartial or independent arrangement.

Prejudicial Access to Witnesses.

A crucial factor in paediatrics is that the doctor must gain the trust and confidence of the parents of the child. Normally parents have the best interests of their child more closely at heart than the GMC or any hospital based ethics committee. The Defendant gained the trust of all twelve parents and none made any complaints about him harming their child or acting unprofessionally in any way. Yet only one of the parents was allowed to attend court to give evidence uniformly in favour of the Defendant's management of their child. All evidence that bears on case should be given full consideration but none of the other parents were permitted to do this. The panel would have witnessed at first hand the types of pressures paediatricians come under from distraught parents wanting something done for their sick child.

Within a Reasonable Time.

Any defendant has a right for his or her case to be heard within a reasonable period of time. The Iraq War killed about 90,000-100,000 civilians at a cost of approximately $700 billions. The hearings of the Iraq War Inquiry (the Chilcot inquiry; www. iraqinquiry.org.uk) lasted about 4 months from November 24th. 2009 to March 2010 in the U.K. The inquiry into the professional misconduct of Professor Walker-Smith lasted more than five years and the costs are yet to be revealed. The reasons given for the delay were the need to study twelve children under review, examining all correspondence and every laboratory test to assess their implications for clinical investigation or clinical research.

Testimonial Evidence.

After determination of misconduct had been announced by the panel in January 20010, Professor Walker-Smith received more than 100 testimonial letters in support of his good character and clinical competence. They came from senior members of the medical profession (Sir Christopher Booth, Professor Sir Nicholas Wright amongst others), from doctors

who had studied for higher degrees with him, from other doctors who had worked with him, from former patients, other colleagues and friends from around the world. The Defence counsel reported that they had never encountered such an impressive bundle of letters of support. Yet the GMC panel appeared to attach no weight to these testimonials when it came to pronouncing their verdict.

Sanctions.

The Prosecution counsel for the GMC ended by insisting that the Professor was guilty of serious professional misconduct and although no injury had been done to any of his patients the ultimate sanction of erasure was recommended. His own evidence as to doing clinical investigation and that of his highly experienced Expert Witness was ignored as was his national and international reputation on how to practice in this field. He was told he was a threat to Public Health and to his patients, although he was then 74 years old and had been completely retired from medical practice for almost nine years. It was insisted he had performed research rather than clinical investigation to find out what was wrong with these 12 children.

The GMC panel recommended erasure from the medical register allegedly for the sake of retaining public trust in the medical profession. After selecting evidence from expert witnesses that suited their own verdict they concluded that his offence had been not to follow the rules laid down by the GMC in all particulars for what they call 'research medicine'; about many of which there is disagreement. The sanctions applied by the GMC appeared to be purely punitive in the nature of making a scapegoat since one cannot protect patients from a doctor who no longer practices medicine due to his age.

Before expulsion was implemented Professor Walker-Smith was granted the opportunity to appeal.

Appeal Before the High Court, London: Walker-Smith v General Medical Council (2012) Case No: CO/7039/2010.

Professor Walker-Smith was to be struck off because it was stated he undertook clinical research without ethical approval according to the requirements of the GMC. The Judge at the High Court in the Royal Courts of Justice quashed both the charges and sanctions after about 4 days of public hearings. The GMC had previously taken 5 years to reach their verdict.

The Honourable Justice Mitting's arguments were as follows.

Benefits to Whom.

The Judge required a universally acceptable definition of clinical research as opposed to clinical investigation; and he started from a simple definition that: 'the aim of medical practice is to benefit the individual patient; the aim of research is to improve the stock of knowledge for the benefit of patients generally'. However these are not mutually exclusive.

The Judge quoted from reports published by the Royal College of Physicians, London (RCP). The guidance entitled On Research involving Patients (London UK 1990) states: 'the distinction between 'medical practice' and 'research' is often less clear than is suggested because both are practised simultaneously'

Intentions of the Doctor.

Another report from the Royal College of Physicians on guidelines on the practice of Ethics Committees in Medical Research involving human subjects (London UK 1996) emphasises the importance of the intention of the doctor: 'The definition of research continues to present difficulties particularly with regards to the distinction between medical practice and medical research. The distinction derives from intent. In medical practice the sole intention is to benefit the individual patient consulting the clinician not to gain knowledge of general benefit, although such knowledge may incidentally emerge from clinical experience. In medical research the primary intention is to advance knowledge so that patients in general may benefit; the individual patient may or may not benefit directly'. When a clinician departs in a significant way from usual practice, and with the patient's consent, the innovation need not constitute research requiring ethical approval according to the RCP, although it may be described as an experiment in the sense that it is novel. The very first injection of insulin into the first comatose diabetic child in 1922 might fall into this category. Injection into the tenth comatose child would clearly be medical care since all nine previous injections were successful in recovering the children. So definitions can change quickly. As a further example in medical practice it is common to publish a case-report in the medical literature which is a combination of clinical investigation (which shows how to diagnose a rare condition in a particular patient) and also clinical research (in that it will benefit future patients who present with similar features).

Another example is a clinical audit study which reports on all the patients in a clinic, with say, heart attacks to find out how many are treated with statins. This will benefit individual patients in the clinic who are not yet taking statins, as well as patients in other clinics as to the possible risks and benefits of statin therapy.

The distinction of intent again falls into the logical fallacy of not being mutually exclusive: a doctor may proceed with one of several intentions in mind. One would therefore have to have some way of ascertaining the strength of motivation of these intentions (as to doing research, to investigation, to care, or to all three in varying combinations) and then to decide where each may lie on the spectrum between pure research (an action that has no medical relationship to the patient's current condition) and pure medical care (an action that only relates to the patient's current condition, such as removing a foreign body from the conjunctival sac). This is clearly an impossible and almost meaningless task.

Professor Walker-Smith's defence was that his intentions and actions were primarily based on 'clinical need' as evidenced in various correspondence with other doctors and therefore more towards the clinical care end of the spectrum. The GMC prosecution did not claim he was lying in this regards, nor did the GMC panel, they just determined that he was working at the clinical research end of the spectrum by accepting evidence from their own expert witnesses and ignoring the evidence of the defence expert witnesses. No legal reasons were given why they made such a choice.

In the words of the Judge, the GMC panel 'had to decide what Professor Walker-Smith thought he was doing: if he believed he was under-taking research in the guise of clinical investigation and treatment he deserved the finding that he had been guilty of serious professional misconduct and the sanction of erasure; if not, he did not, unless his actions fell outside the spectrum of that which would have been considered reasonable medical practice by an academic clinician'. There appeared no way to resolve this and hence the Judge's decision to quash the charges and sanctions.

Conclusions.

In view of the lack of clear definitions and complex motivation to action (care, investigation, research, or all in varying degrees) it is surprising that the inexpert GMC panel could be so authoritarian about the meaning of the term 'medical research' as to attempt to expel Professor Walker-Smith from his profession to which he has given a life-long and truly dedicated service.

The first trial was a hapless legal episode resulting in much time, much personal anguish for the Defendant and much money being expended in arguments about ill-defined rules adopted by the GMC; when the underlying ethical principles were barely considered. Ethical rules are derived from such fundamental principles in Western Society (Great Charters, London 1979) as 'beneficence', 'autonomy', and 'fairness' and rules derived from these should not have the force of law if they conflict with rules of application adopted by other Institutions. When in dispute perhaps the Law Courts are not the best place to attempt resolution. Such cases may be better adjudicated by such bodies as the Nuffield Council of Bioethics UK where a less adversarial position of either winning or losing can be taken. One last point the Judge made was that 'it would be a misfortune if this were to happen again' which we take to mean there is no case for making scapegoats in the British Justice system.

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